UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES
Antimicrobial Division

April 13, 2005

SUBJECT: PRODUCT CHEMISTRY REVIEW OF: **EMIL**

DP Barcode: D313000

Reg. No. or File Symbol 5813-IL

TGAI/Manufacturing-use Product [ ] OR End-use Product [X]

TO: Wanda Mitchell
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APPLICANT: Clorox Company.

Action code: A54
Due date: 05/24/05

Product Formulation **Active Ingredient(s)**	**% by wt.**
Sodium hypochlorite	0.0095

Inert ingredient information may be entitled to confidential treatment

Product ingredient source information may be entitled to confidential treatment

BACKGROUND:

The registrant, Clorox Company, submits a summary physical/chemistry property for review. However, the application for pesticide shows that the registrant is submitting storage stability and corrosion characteristics data. The non-integrated end-use product, **EMIL,** is intended to be a kitchen sanitizing spray (food-contact surface sanitizer).

FINDINGS:

1. The Product Chemistry Reviewer has received the following documents:
   - Confidential Statements of Formula (CSFs), dated 01/20/05, for the basic and the alternate (A01, A02, & A03) formulations.
   - A label, dated 01/20/05.
   - A letter, dated 01/20/05.
   - Application for Pesticide, dated 01/20/05.
   - Data waiver requests, dated 01/20/05.
   - A data matrix, dated 01/20/05 EPA Form 8570-35.
   - Study title "Product Chemistry - Emeril," dated 01/12/05 MRID #464524-01.

2. The CSF, dated 01/20/05, for the basic formulation and the alternate (A01, A02, & A03) formulations are revised.

3. Note that while the product name in the study, MRID #464524-01, is given as Emeril, it is listed as Emil in the Confidential Statement of Formula (CSF), and on the label.

4. The registrant reported the total percentage by weight as 100.0226% for the alternate formulation "A01," and 99.9178% total percentage by weight for alternate formulation "A02."

5. The product contains [redacted] components. However, in the CSF only [redacted] components are accounted for the total percentage by weight. The [redacted] component does not show the amount or percentage by weight in column 13. However, the registrant reported the certified limits in column 14.

6. The registrant did not indicate the name and address for the alternate source, [redacted] of the active ingredient(AI) in the CSF for the basic formulation.

7. The upper limits for the AI do not meet the EPA standard limits for the basic and the alternate (A01, A02, & A03) formulations.

8. The registrant is requesting a wider limit for the AI based on a multiple studies performed on the product. However, the registrant has not provided any data that support a wider range for the upper certified limit.

9. The inert, [redacted] does not meet the EPA standard upper-certified limits.

10. The CSF for the basic formulation and the label do not have the same nominal.

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11. The applicant has not provided nominal concentrations in the product for all formulation ingredients, has not correctly calculated the certified limits, has not provided a certification for the certified limits, and has not indicated the production batch size or the QC measures taken during the formulation process.

12. The registrant has not declared the equivalent available free chlorine on the label.

13. The registrant did not expand the 830.1550 Product Identity and Composition. In page 3 of 20 (MRID #464524-01) shows the title of the 830.1550 only.

14. The 830.1750 Certified Limits documentation is incomplete.

15. The equation to obtain the percentage of sodium hypochlorite in the enforcement analytical method shows a typo in the final expression of the equation. The equation appears to express the percentage in "ml/wt," in other words volume/weight.

RECOMMENDATION:

1. The registrant must report the total percentage by weight as 100% in all CSFs.

2. The registrant needs to include column 13 for the [redacted] component, [redacted].

3. The registrant needs to correct the name of the alternate source, [redacted], from [redacted]

4. The registrant should provide data to support a wider limit.

5. The registrant should change the upper certified limit for [redacted] from [redacted]

6. The registrant needs to adjust the amount in column 13a for the basic formulation for the AI when [redacted] sources have different purity (column 10). Therefore, the registrant needs to remove one of the sources and report it as an alternate formulation.

7. The registrant should document the 830.1550 Product Identity and Composition.

8. The registrant should complete the certified limits for all components.

9. The registrant needs to correct the final equation of the active ingredient (AI) from ml/weight to g/weight.

10. The registrant should upgrade the guideline stated in the 830 guideline tables (below) that are indicated as "U & G."

CONCLUSION:

The CSFs, dated 01/20/05, for the basic formulation and the alternate (A01, A02, & A03) formulations are not acceptable. The registrant must comply with the requirements, recommendations and issues listed above.

PRODUCT CHEMISTRY REVIEW

11. CONFIDENTIAL STATEMENT OF FORMULA

11a. Type of formulation and source registration

- Non-integrated formulation system [X]
  - Are all TGAIs used registered? Yes [X] No [ ]
- Integrated formulation system [ ]
- If "ME-TOO", specify EPA Reg. # of existing product:

11b. Clearance of inerts for non-food or food use:
Cleared for food use under 40 CFR §180.1001: Yes [X] No [ ] NA [ ]

11c. Physical state of product: liquid

11d. The chemical IDs and analytical information (including that for the TGAIs), density, pH, and flammability are consistent with that given in 830, Part B
Yes [X] No [ ] *Flammability N/A.* See FINDINGS.

11h. NCs and CLs are acceptable: Yes [ ] No [X] *See FINDINGS.*

11i. Active ingredient(s)	NC	LCL	UCL
A. Sodium hypochlorite	0.0095%	0.0085%	0.017%

11j. For products produced by an integrated formulation system:

- All impurities of toxicological significance have a UCL?
  Yes [ ] No [ ] Not applicable [X]
- All impurities of $\geq$ 0.1% in the product have been identified?
  Yes [ ] No [ ] Not applicable [X]

12. PRODUCT LABEL

12a. The active ingredients statement (chemical IDs and NC] is consistent with the CONFIDENTIAL STATEMENT OF FORMULA? Yes [X] No [ ]

12b. The formulation contains one of the following:

- 10% or more of a petroleum distillate: Yes [ ] No [X]
- 1.0% or more of methyl alcohol: Yes [ ] No [X]
- Sodium nitrite at any level: Yes [ ] No [X]
- a toxic List 1 inert at any level: Yes [ ] No [X]
- arsenic in any form: Yes [ ] No [X]

12c. If Yes to any of the above, does the inert ingredients statement contain a footnote indicating this? Yes [ ] No [ ] Not applicable [X]

12d. The appropriate warning statement regarding flammability or explosive characteristics of the product are listed on the label?
Yes [X] No [ ] Not applicable [ ] *Flammability and Explodability N/A. See FINDINGS.*

12e. The storage and disposal instructions for the pesticide and container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses? Yes [ ] No [X]
Product contains Sodium Hypochlorite as an active ingredient. The following applicable statement for this type of compound was not provided in the label: "Store this product in a cool dry area, away from direct sunlight and heat to avoid deterioration. In case of spill, flood areas with large quantities of water. Product or rinsates that cannot be used should be diluted with water before disposal in a sanitary sewer. Do not reuse empty container but place in trash collection. Do not contaminate food or feed by storage, disposal or cleaning of equipment."

12f. Does the product require an expiration date at which time the NC falls below the LCL (based on the one year storage stability data or other information)?
Yes [ ] No [ ] *Storage Stability and Corrosion Characteristics Studies are underway. See FINDINGS.*

13. **PRODUCT CHEMISTRY (830 Series, Part A)**

13a. Data Requirements	Acceptance of Information	MRID No.
830.1550[1] Product Identity	G	464524-01
830.1600 Description of Materials	A	464524-01
830.1620 Production Method[2]	NA	
830.1650 Formulation process[3]	A	464524-01
830.1670 Formation of impurities[4]	NA	464524-01
830.1700 Preliminary Analysis[5]	NA	
830.1750 Certified Limits[6]	G	464524-01
830.1800 Analytical Method[7] Sodium hypochlorite by titrometric determination	U	464524-01

Explanation: A=acceptable; N=not acceptable; NA=technically not applicable; G=data gap; U=requires upgrading; W=waived; E=EPA estimate.

[1]See Confidential Appendix A for additional information
[2]For MP/EP products produced by an integrated formulation system.
[3]For products from a TGAI or MP.
4May be waived unless actual/possible impurities are of toxicological concern.
[5]Five batch analysis required for products produced by an integrated formulation system.
[6]If different from standard CLs recommended in 40 CFR 158.175, this should be discussed in Confidential Appendix A.
[7]Abbreviate method used as follows: gas chromatography (GC), infrared (IR), ultraviolet absorption (UV), nuclear magnetic resonance (NMR), etc.

Physical and Chemical Characteristics (Series 830, Part B)

13b. Physical/Chemical Properties*	Acceptance of data	Value or qualitative description	MRID No.
830.6302 Color	A	NA	464524-01
830.6303 Physical state	A	liquid	464524-01
830.6304 Odor	NA		
830.6313 Stability to normal & elevated temperature, metals, & metal ions	NA		
830.6314 Oxidation/Reduction	A	+0.90 volts	464524-01, 432329-01
830.6315 Flammability	A	NA. The product does not contain combustible liquids.	464524-01
830.6316 Explodabililty	A	NA. The product is not potentially explosive.	464524-01
830.6317 Storage stability	A	The stability study is ongoing.	464524-01
830.6319 Miscibility[2]	A	The product is not an emulsifiable liquid and it is not to be diluted with petroleum solvents.	464524-01
830.6320 Corrosion Characteristics		The corrosion study is ongoing.	464524-01
830.6321 Dielectric breakdown	A	The product is not intended to be used around electrical equipment.	464524-01
830.7000 pH[1]	A	7.47	464524-01
830.7050 UV/Visible Absorption	NA		
830.7100 Viscosity	A	0.73 cps @ 40°C and 1.1 cps @ 20°C	464524-01
830.7200 Melting point	NA		
830.7220 Boiling Point/Boiling Range	NA		
830.7300 Density/Relative density/bulk density		1.00 g/mL (8.34 lb/gal)	464524-01
830.7370 Dissociation constants in water	NA		
830.7520 Particle size, fiber length, & diameter distribution	NA		
830.7550 Partition coefficient(n-octanol/water), shake flask method	NA		
830.7560 Partition coefficient(n-octanol/water), generator column method	NA		
830.7570 Partition coefficient(n-octanol/water),	NA		
830.7840 Water solubility: Column elution method; shake flask method	NA		
830.7860 Water solubility, generator column method	NA		
830.7950 Vapor pressure	NA		

Explanation: A=acceptable; N=not acceptable; NA=technically not applicable; G=data gap; U=requires upgrading; W=waived; E=EPA estimate.

* Provide brief description, e.g., color--yellow or property value, e.g., density 1.25 g/cc; Unless otherwise indicated, the property should be at 25°C.

[1] If product is dispersible with water
[2] If product is an emulsifiable liquid